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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/696,370  | 10/28/2003  | David Emil Edgren    | AR02164USA CON1     | 6792             |
| 27777   | 7590        | 06/21/2005           | EXAMINER            |                  |
| PHILIP S. JOHNSON<br>JOHNSON & JOHNSON<br>ONE JOHNSON & JOHNSON PLAZA<br>NEW BRUNSWICK, NJ 08933-7003 |             |                      | WEBMAN, EDWARD J    |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1616                |                  |

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                  |               |
|------------------------------|------------------|---------------|
| <b>Office Action Summary</b> | Application No.  | Applicant(s)  |
|                              | 10/696,370       | EDGREN ET AL. |
|                              | Examiner         | Art Unit      |
|                              | Edward J. Webman | 1616          |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 11 March 2005.  
 2a) This action is FINAL.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1, 8-12 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1 and 8-12 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
     Paper No(s)/Mail Date 2/19/04.

4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

Applicant is advised that applicants' second amendment filed 3/11/05 adding claims 10-12 is not in compliance with rule 121 because applicants did not recite claims 1, 8, and 9 which are still pending according to applicants' second remarks filed 3/11/05 indicating applicants' intention to prosecute claims 1, 8-12. A correct set of claims is recommended with applicants' next response.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Husbands et al (US 4,761,501) in view of Theeuwes (US 4,111,201) and Fuisz (US 5,407,676).

Husbands et al teach substituted phenylacetamides such as venlafaxine as antidepressants (column 8, lines 22-27). Delivery by "any of the usual dosage forms, including tablets and capsules" is disclosed (column 10, lines 35-37).

However, Husbands does not teach the claimed dosage form.

Theeuwes teaches an osmotic device for delivery of an agent at a controlled rate comprising an agent, a compartment, a semipermeable wall, a passageway and a member which increases in volume, whereby the agent is released(abstract). Antidepressants are specified (column 2 line 22). Delivery of highly soluble agents is disclosed (column 2 lines 6-11). Tablet shaped devices are specified (column 20 line

55). Polyoxyalkylene ethers and hydroxyethyl cellulose are disclosed as suspending agents for the active (column 12 lines 7- 30).

It would have been obvious to one of ordinary skill to deliver the antidepressant of Husbands et al in the vehicle of Theeuwes to achieve the beneficial effect of delivery at a controlled rate.

As the claimed maltodextrin, Fuisz teaches its equivalence to hydroxyethyl cellulose as a carrier (column 5 lines 10-22).

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 8 (d) "a displacement in" is indefinite; do applicants intend "composition" after "displacement"? See Claim 9 (d).

Claims 1, 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 9, 10, and 11 the language "wherein the dotted line represents an unsaturated or a cycloalkenyl group" appears to exclude venlafaxine wherein the ring is saturated, contradicting claims 13, 14. Do applicants intend to precede the word "unsaturated" with "optional"?

Claims 8 and 9 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 6 and 7 of copending Application No. 08/442292. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The only difference in the claims is the language "controlled-release" in the preamble of claims 6 and 7, to which the examiner gives no weight in view of the identical claim language in the body of the claims.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, G. Kunz, can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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